

REMARKS

The final Office Action dated December 13, 2006, has been carefully considered. Claims 20-37 were pending. After entry of this amendment, claims 20-31, 33, and 38-41 will be pending. Claims 20 and 26 have been amended. Claim 20 has been amended to more particularly point out and claim a certain embodiment of the present invention. Support for this amendment can be found in the originally-filed application at, for example, originally-filed claims 1, 11, and 15. Claim 26 has been amended to correct a typographical error. Support for this amendment can be found in the originally-filed specification at, for example, originally-filed claim 7. Claims 32 and 34-37 have been cancelled without prejudice. Applicant reserves the right to pursue the subject matter of the cancelled claims in one or more related applications. Claims 35 and 37 have been rewritten as new claims 38 and 39, respectively. New claims 40 and 41 have been added and find support in the originally-filed specification at, for example, page 5, lines 16-18; and page 7, lines 25-27.

No new matter has been introduced.

Reconsideration of the present application in view of the above amendments and the following remarks is respectfully requested.

I. CLAIM REJECTIONS UNDER 35 U.S.C. 103(a)

A. Claims 20-30 are Patentable over U.S. Patent No. 6,355,058 to Pacetti *et al.* ("Pacetti") in view of U.S. Patent No. 4,749,125 to Escallon *et al.* ("Escallon") and U.S. Patent No. 6,056,993 to Leidner *et al.* ("Leidner")

Claims 20-30 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Pacetti in view of Escallon and further in view of Leidner. This rejection is traversed.

Independent claim 20 recites a method for coating at least a portion of a medical device including, *inter alia*, providing an implantable medical device that has a portion that has a surface adapted for exposure to body tissue of a patient, and applying to the surface a coating formulation comprising a polymeric material and a solvent selected from a group consisting of tetrahydrofuran, chloroform, toluene, acetone, isooctane, 1,1,1-trichloroethane and mixtures thereof, wherein the polymeric material is about 1 to about 15 weight % of the coating formulation by: (1) providing a nozzle apparatus comprising a chamber connected to at least one opening for dispensing the coating formulation; (2) placing the coating formulation into the chamber; (3) electrically charging the coating formulation; (4) creating

droplets of the electrically charged coating formulation; and (5) depositing the droplets of coating formulation onto the grounded surface to form a coating on the surface. Claims 21-30 depend from claim 20, and thus also include those limitations.

As discussed in the Amendments filed November 5, 2004, and June 21, 2006, Pacetti does not disclose or suggest the presently claimed method for coating at least a portion of a medical device using a nozzle apparatus in which the coating formulation is first electrically charged before the coating formulation is formed into droplets that are electrically charged. The mere disclosure in Pacetti that electrostatic liquid spraying can be used does not teach or suggest the present method, which, unlike conventional electrostatic spraying methods, first electrically charges the coating formulation and then forms droplets from such charged formulation. Pacetti does not provide any indication that the electrostatic spraying method that it mentions is a method other than the conventional electrostatic spray coating method.

Also, as acknowledged by the Examiner, Pacetti does not disclose or suggest applying to the surface of an implantable medical device a coating formulation that comprises a solvent selected from a group consisting of tetrahydrofuran, chloroform, toluene, acetone, isooctane, 1,1,1-trichloroethane and mixtures thereof, as recited in claim 20. In addition, Pacetti does not disclose or suggest that the polymeric material is about 1 to about 15 weight % of the coating formulation, as recited in claim 20.

Escallon does not remedy the deficiencies of Pacetti. As acknowledged by the Examiner, Escallon also does not disclose or suggest applying to the surface of an implantable medical device a coating formulation that comprises a solvent selected from a group consisting of tetrahydrofuran, chloroform, toluene, acetone, isooctane, 1,1,1-trichloroethane and mixtures thereof, as recited in claim 20. In addition, Escallon does not disclose or suggest that the polymeric material is about 1 to about 15 weight % of the coating formulation, as recited in claim 20.

Moreover, as discussed in the Amendments filed November 5, 2004, and June 21, 2006, Escallon does not disclose or suggest a method for coating at least a portion of an implantable medical device, wherein the portion has a surface adapted for exposure to body tissue of a patient as recited in the present claims. Accordingly, Escallon does not disclose or suggest “providing an implantable medical device having a portion that has a surface adapted for exposure to body tissue of a patient” and grounding and applying a coating formulation to the surface of such device, as recited in claim 20.

In addition, there is no motivation in the disclosures of Pacetti and Escallon to combine the teachings of these references to obtain the presently claimed invention. In particular, there is no teaching in Pacetti that an electrostatic spray-coating method in which a

coating formulation is first electrically charged and then formed into droplets should be used to coat an implantable medical device, and Escallon fails to provide any teaching or suggestion that its device should be used to coat implantable medical devices.

Even if there was motivation to combine, Pacetti and Escallon both fail to disclose or suggest applying a coating formulation that comprises: (1) a solvent selected from a group consisting of tetrahydrofuran, chloroform, toluene, acetone, isooctane, 1,1,1-trichloroethane, and mixtures thereof; and (2) a polymeric material that is about 1 to about 15 weight % of the coating formulation, as recited in claim 20.

Leidner does not remedy the deficiencies of Pacetti and Escallon. Leidner is directed to methods of making a fibrous prosthesis by extruding fibers over a rotating mandrel. (Column 1, lines 15-17). Like Pacetti and Escallon, Leidner also does not disclose or suggest applying to the surface of an implantable medical device a coating formulation that comprises a polymeric material and a solvent, wherein the polymeric material is about 1 to about 15 weight % of the coating formulation. In addition, as discussed in the previous Amendments, Leidner does not disclose or suggest a method of coating a medical device. In particular, Leidner does not disclose or suggest a method that includes the step of grounding the surface of the medical device. Leidner also does not disclose or suggest creating *droplets* of the electrically charged coating formulation, and depositing the droplets of coating formulation on the grounded surface to form a coating, as recited in claim 20.

One skilled in the art would not find motivation in Pacetti, Escallon, or Leidner to combine the teachings of these references to obtain the presently claimed invention. Pacetti and Leidner do not disclose or suggest that an electrostatic spray-coating method in which a coating formulation is first electrically charged and then formed into droplets should be used to coat an implantable medical device, and Escallon fails to provide any teaching or suggestion that its device should be used to coat implantable medical devices.

Moreover, the combination of Pacetti, Escallon and Leidner would not even result in the presently claimed invention since none of these references disclose or suggest applying a coating formulation comprising a solvent and a polymeric material to an implantable medical device, wherein the polymeric material is about 1 to about 15 weight % of the coating formulation.

Thus, claim 20 and the claims depending therefrom are believed to be patentable over Pacetti in view of Escallon and Leidner. Accordingly, withdrawal of this rejection and allowance of claims 20-30 are respectfully requested.

B. Claims 20-30 Are Patentable Over Pacetti In View Of Escallon And U.S. Patent No. 5,695,458 To Shikani *et al.* (“Shikani”)

Claims 20-30 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Pacetti in view of Escallon and Shikani. This rejection is traversed.

Claims 20-30 were shown above to be patentable over Pacetti and Escallon. Shikani does not remedy the deficiencies of Pacetti and Escallon.

Shikani also does not disclose or suggest applying to the surface of an implantable medical device a coating formulation that comprises a polymeric material and a solvent, wherein the polymeric material is about 1 to about 15 weight % of the coating formulation. In addition, as discussed in the June 21, 2006 Amendment, Shikani also does not disclose or suggest a method of coating an implantable medical device that comprises providing an implantable medical device that has a portion that has a surface adapted for exposure to body tissue of a patient. Instead, Shikani is directed to “anti-infective coatings for *non-implantable* medical devices.” (Column 2, lines 16-18). (Emphasis added). Thus, Shikani does not disclose or suggest and in fact teaches away from providing an implantable medical device as presently claimed.

Thus, Pacetti, Escallon, and Shikani, whether taken alone or in combination, do not disclose or suggest applying to the surface of an implantable medical device a coating formulation that comprises a polymeric material and a solvent, wherein the polymeric material is about 1 to about 15 weight % of the coating formulation.

Therefore, it is believed that claim 20 and the claims depending therefrom are patentable over Pacetti, Escallon, and Shikani. Accordingly, withdrawal of this rejection and allowance of claims 20-30 are respectfully requested.

C. Claims 20-30 and 33 are Patentable over U.S. Patent Application No. 2002/0081732 to Bowlin *et al.* (“Bowlin”)

Claims 20-30 and 33 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bowlin. This rejection is traversed.

Bowlin cannot be applied as a reference under 35 U.S.C § 103(a). The present application claims priority to U.S. Patent Application Number 09/954,579, filed September 18, 2001. Bowlin was filed on October 18, 2001, and claims the benefit of provisional application no. 60/241,008 (“the ‘008 application”), filed October 18, 2000, and provisional application no. 60/270,118 (“the ‘118 application”), filed February 22, 2001. For Bowlin to apply as prior art, there must be support in one of these provisional applications. As discussed in the Amendment filed June 21, 2006, and discussed below, Bowlin cannot be

considered a prior art reference to the presently claimed invention because the provisional applications do not provide such support.

For instance, the '008 and '118 applications both fail to disclose or suggest applying a coating formulation that comprises a solvent selected from a group consisting of tetrahydrofuran, chloroform, toluene, acetone, isooctane, 1,1,1-trichloroethane, and mixtures thereof, and a polymeric material that is about 1 to about 15 weight % of the coating formulation, as recited in claim 20.

Also, the '008 application does not disclose or suggest a method of coating an implantable medical device that includes the steps of creating *droplets* of an electrically charged coating formulation, and depositing the *droplets* of coating formulation on to the grounded surface of a medical device to form a coating, as recited in the presently claimed invention. The Examiner cites claims 21-27 of the '008 application as support for the Bowlin disclosures. However, claims 21-27 of the '008 application are directed to depositing collagen *fibers* on a substrate. The '008 application does not disclose depositing *droplets*, as recited in present claim 20. Also, the Examiner cites U.S. Patent No. 6,592,623 ("the '623 patent"), which is incorporated by reference into the '008 application, for support. However, the '623 patent is directed to an electrospinning process to form fibers (*see, e.g.,* column 4, lines 23-27), not to a process for forming droplets as recited in present claim 20.

The '118 application also does not disclose or suggest a method of coating an implantable medical device by grounding the surface, providing a nozzle apparatus, placing the coating formulation comprising a polymer and a solvent into the chamber, creating droplets of the electrically charged coating formulation, and depositing the droplets of coating formulation on to the grounded surface to form a coating, as recited in the presently claimed invention.

It is noted that an Examiner's conclusory statements cannot form a basis for a *prima facie* case of obviousness. *In re Sang-Su Lee*, 277 F.3d 1338, 1343-4 (Fed. Cir. 2002).

Since the provisional applications do not provide support for the disclosures in Bowlin, and Bowlin does not have a filing date before September 18, 2001 (the filing date of the parent application of the present application), Bowlin cannot be considered a prior art reference to the present invention.

Thus, withdrawal of this rejection and allowance of claims 20-30 and 33 are respectfully requested.

II. ALLOWABLE CLAIMS

The Examiner indicated that claims 31, 35, and 37 are objected to as being dependent upon rejected base claims 20, 34, and 36, respectively, but would be allowable if rewritten in independent form including all of the limitations of the base claims. Applicants disagree with this objection. Claim 20 has been amended to expedite prosecution and is believed to be patentable for the reasons discussed above. Thus, it is believed that claim 31 which depends from claim 20 is also patentable. Also, claims 35 and 37 have been cancelled and rewritten as claims 38 and 39, respectively, solely to expedite prosecution. Thus, claims 38 and 39 are believed to be allowable. Accordingly, withdrawal of this objection and allowance of claims 31, 38, and 39 are respectively requested.

III. NEW CLAIMS 40 AND 41

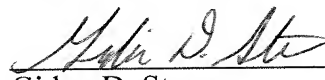
New claims 40 and 41 have been added. These claims depend from claim 20 and, for the reasons discussed above, are believed to be patentable over the references cited herein. Accordingly, allowance of claims 40 and 41 is respectfully requested.

IV. CONCLUSION

In view of the above remarks and amendments, it is believed that the claim rejections and claim objections have been overcome and that the pending and new claims are in condition for allowance. Reconsideration and allowance of the present application are respectfully requested. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicant's position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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Gidon D. Stern

(Reg. No. 27,469)

By:


Linda B. Azria

(Reg. No. 44,516)

JONES DAY

222 East 41st Street

New York, New York 10017

(212) 326-3939

Enclosures